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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,260	04/09/2004	Michael Coyle	85167-73300	2689

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EXAMINER

TOTH, KAREN E

ART UNIT	PAPER NUMBER
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3735

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,260	COYLE ET AL.	
	Examiner	Art Unit	
	Karen E. Toth	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
 4a) Of the above claim(s) 1-40 and 71-74 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 57-70 is/are allowed.
- 6) ☒ Claim(s) 41-46 is/are rejected.
- 7) ☒ Claim(s) 47-56, 78 and 79 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

3DETAILED ACTION

Election/Restrictions

1. Claims 1-40 and 71-74 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 29 September 2006.
2. Applicant's election with traverse of invention III, claims 41-70, 78, and 79, and linking claims 75-77, in the reply filed on 29 September 2006 is acknowledged. The traversal is on the ground(s) that the entire grouping of claims belong together because invention III is used to recognize respiratory events, from a group of volume signals (invention II) that are derived from respiratory signals (invention I). This is not found persuasive because invention II may be used to process respiratory signals materially different from those collected by invention I. Invention III may be used to process a respiratory signal in materially different fashion than in invention II. Further, no argument has been made as to why invention IV should remain with the other inventions.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 41, 43-44, and 46 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni (US Patent Application Publication 2004/0111040).

Regarding claim 41, Ni discloses a method for recognizing respiratory events comprising deriving a signal indicative of lung volume from a plurality of respiratory signals from a monitored subject (paragraphs [0045], [0051]-[0052], [0058]); deriving one or more temporal sequences of one or more respiratory parameters from the lung volume signal (paragraphs [0053]-[0055]); and recognizing one or more respiratory events in dependence on at least one of the derived temporal sequences of respiratory parameters (paragraphs [0055]-[0056], [0059]).

Regarding claim 43, Ni further discloses deriving temporal sequences of inspiratory and/or expiratory volume parameters from the lung volume signal (paragraph [0109]-0110], [0117]-[0118]).

Regarding claim 44, Ni further discloses recognizing periods of apnea as dependent on volume parameters being less than a threshold apneic volume, where the

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threshold varies in dependence on running median baseline lung volumes and/or on the period during which lung volumes were less than the threshold being longer than a threshold apneic time (paragraphs [0109]-[0112], [0117], [0120]).

Regarding claim 46, Ni further discloses that periods of hypopnea are recognized in dependence on the volume parameters being less than a threshold hypopneic volume but greater than a threshold apneic volume, wherein the threshold volumes vary in dependence on running median baseline volumes and/or on the period during which lung volumes were between the thresholds being longer than a threshold hypopneic time (paragraph [0118]).

5. Claim 41 is rejected under 35 U.S.C. 102(b) as being anticipated by Sackner (US Patent 6015388).

Regarding claim 41, Sackner discloses a method for recognizing respiratory events comprising deriving a signal indicative of lung volume from a plurality of respiratory signals from a monitored subject (column 14, lines 50-53); deriving one or more temporal sequences of one or more respiratory parameters from the lung volume signal (column 14, lines 38-41; column 16, lines 32-38); and recognizing one or more respiratory events in dependence on at least one of the derived temporal sequences of respiratory parameters (respiratory drive may be considered a respiratory event; column 16, lines 32-38).

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6. Claims 41 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by Kihara (US Patent Application Publication 2004/0143194).

Regarding claim 41, Kihara discloses a method of monitoring respiration comprising deriving a signal indicative of lung volume from a plurality of respiratory signals gathered from a monitored subject (paragraphs [0008]-[0009], [0020]); deriving one or more temporal sequences of one or more respiratory parameters from the lung volume signal (paragraphs [0020]-[0021], [0122], [0125]-[0126]); and recognizing one or more respiratory events dependent on at least one of the derived temporal sequences of respiratory parameters (paragraphs [0125]-[0126]).

Regarding claim 43, Kihara further discloses deriving temporal sequences of inspiratory and/or expiratory parameters from the lung volume signal (paragraphs [0125]).

7. Claims 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Anderson (US Patent 4463764).

Regarding claim 41, Anderson discloses a method of monitoring respiration comprising deriving a signal indicative of lung volume from a plurality of respiratory signals gathered from a monitored subject (column 2, lines 5-28; column 5, lines 9-15); deriving one or more temporal sequences of one or more respiratory parameters from the lung volume signal (column 6, lines 14-17); and recognizing one or more respiratory events dependent on at least one of the derived temporal sequences of respiratory parameters (column 15, lines 46-50).

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Regarding claim 42, Anderson further discloses recognizing artifacts by applying one or more rules to the sequences of respiratory parameters and discarding portions of the sequences and the corresponding lung volume signal recognized to be artifacts (column 2, lines 40-44; column 7, lines 23-42; column 10, lines 34-39).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kihara in view of Ni.

Regarding claim 45, Kihara discloses all the elements of the current invention, as described above, and further discloses using dependence on a phase relation between a signal reflective of rib cage size and a signal reflective of abdominal size to identify

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various periods (paragraphs [0009], [0021], [0194]), and that the system may be used to diagnose apnea (paragraph [0003]). However, Kihara does not disclose recognizing periods of apnea as dependent upon volume parameters being less than a threshold apneic volume that depends upon median baseline lung volumes and/or a threshold period of time where volumes are lower than the threshold.

Ni teaches recognizing periods of apnea as dependent on volume parameters being less than a threshold apneic volume, where the threshold varies in dependence on running median baseline lung volumes and/or on the period during which lung volumes were less than the threshold being longer than a threshold apneic time (paragraphs [0109]-[0112], [0117], [0120]), in order to accurately identify apneic periods from physical parameter signals. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Kihara and diagnosed the apnea as dependent on volume parameters being less than a threshold apneic volume, where the threshold varies in dependence on running median baseline lung volumes and/or on the period during which lung volumes were less than the threshold being longer than a threshold apneic time, as taught by Ni, in order to accurately identify apneic periods from physical parameter signals.

10. Claims 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kihara in view of Anderson and Watson (US Patent 4834109).

Regarding claim 75, Kihara discloses deriving a signal (V_t) indicative of lung volume from a combination of at least one filtered signal indicative of rib cage (RC) size

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and at least one signal indicative of abdominal (AB) size (paragraphs [0010], [0020]-[0021]); deriving one or more temporal sequences of one or more respiratory parameters from the Vt signal (paragraphs [0020]-[0021], [0122], [0125]-[0126]); and recognizing one or more respiratory events dependent on at least one of the derived temporal sequences of respiratory parameters (paragraphs [0125]-[0126]). Kihara does not disclose filtering the respiratory signals, nor performing a calibration procedure that includes discarding outlier values from the signals.

Anderson teaches filtering respiratory signals to reduce non-respiratory signal components (column 7, lines 34-42); and recognizing and discarding artifacts from a lung volume signal (column 7, lines 23-33; column 10, lines 34-39), in order to increase the accuracy of measured respiratory parameters.

Watson teaches monitoring a patient's lung volume via RC and AB signals, where the linear combination of the RC and AB signals adaptively responds to the subject's behavioral state (column 4, lines 25-30); and where at least one coefficient of the linear combination is derived from a calibration procedure comprising selecting sets of inspiratory and/or expiratory volumes from concurrent RC and AB signals (column 4, lines 64-67), performing a multi-step process to detect and discard outlier values from the RC and AB signals (column 7, lines 46-48), and deriving at least one coefficient from the RC and AB volume sets (column 7, lines 39-52; column 8, lines 50-67), in order to increase the accuracy of the linear combination of signals.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Kihara with the steps of filtering

signals to reduce non-respiratory components, as taught by Anderson, in order to increase the signals' accuracy, and performing a calibration procedure to obtain a linear coefficient where outlier values are discarded, as taught by Watson, in order to increase the accuracy of the linear combination of signals.

Regarding claim 76, Kihara further discloses a computer system for processing respiratory signals comprising a processor, and memory connected to the processor, where the memory contains instructions for causing the processor to perform the methods of monitoring a patient's respiration, such as described regarding claim 75 above (paragraphs [0035]-[0037] and [0097]-[0098]).

Regarding claim 77, Kihara further discloses a program product for processing respiratory signals comprising a computer readable medium with instructions for causing the system to monitor a patient's respiration, such as described regarding claim 75 above (paragraphs [0035]-[0037]).

Allowable Subject Matter

11. Claims 47-56 and 78-79 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the method of claims 47 and 48, including, *inter-alia*, recognizing a breath as an artifact if it does not meet the "true breath rule" – that is, a breath is considered a "true breath" if the difference between the previous breath's end expiratory volume and the current breath's end

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expiratory volume is less than a fixed ratio times V_{t-cal} , where the ratio is preferably between 200% and 300%.

The prior art of record fails to anticipate or make obvious the method of claim 49, including, *inter-alia*, recognizing periods of speech by a subject as dependent upon inspiratory/expiratory ratio, fractional inspiratory time, inspiratory flow rate, and/or expiratory time as derived from a measured lung volume signal.

The prior art of record fails to anticipate or make obvious the method of claim 50, including, *inter-alia*, recognizing dyspnea, or shortness of breath, as dependent upon the ratio of minute ventilation volume to peak expiratory flow, as derived from a measured lung volume signal.

The prior art of record fails to anticipate or make obvious the method of claim 51 including, *inter-alia*, calculating the ratio of FEV to VC and recognizing a change in the ratio as being dependent upon the ratio of time to reach peak expiratory flow to expiratory time.

The prior art of record fails to anticipate or make obvious the method of claim 52 including, *inter-alia*, calculating the ratio of FEV to VC and recognizing a change in the ratio as being dependent upon the ratio of peak inspiratory flow to tidal volume.

The prior art of record fails to anticipate or make obvious the method of claim 53 including, *inter-alia*, calculating the ratio of FEV to VC and recognizing a change in the ratio as being dependent upon the ratio of peak expiratory flow and mean expiratory flow.

The prior art of record fails to anticipate or make obvious the method of claim 54 including, *inter-alia*, calculating the ratio of FEV to VC and recognizing a change in the ratio as being dependent upon the rib cage's contribution to the tidal volume.

The prior art of record fails to anticipate or make obvious the method of claims 55, 78, and 79 including, *inter-alia*, calculating the ratio of FEV to VC and recognizing a change in the ratio as being dependent upon a temporal sequence of the fraction of expiration time with thoraco-abdominal asynchrony as derived from signals reflective of rib cage size and abdominal size.

The prior art of record fails to anticipate or make obvious the method of claim 53 including, *inter-alia*, calculating the ratio of FEV to VC and recognizing a change in the ratio as being dependent upon the ratio of peak inspiratory flow to tidal volume.

12. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to anticipate or make obvious the method of claims 57-70, including, *inter-alia*, determining the occurrence of a cough when both sound event signals and lung volume signals showing cough event characteristics temporally coincide.

Gavriely (US Patent 6261238) discloses recognizing a candidate cough sound event when a sound signal from a microphone recording vocalizations exceeds a threshold, comparing the sound signal to a respiration monitor to ensure that the sound coincides with a respiration event, and determining that a cough has occurred based on

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the sound signals. Gavriely does not disclose additionally filtering a lung volume signal in response to characteristics of the sound event, recognizing a candidate event based on tidal volume signals exceeding a threshold, and determining the cough's occurrence only when the lung volume and sound signals coincide.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent Application Publication 2006/0178591 to Hempfling, which discloses a similar method.

US Patent 6436057 to Goldsmith, which discloses a similar method of respiratory monitoring.

US Patent 4796639 to Snow, which discloses a similar method of respiratory monitoring.

US Patent Application Publication 2004/0249299 to Cobb, which discloses a similar method of respiratory monitoring.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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ROBERT L. NASSER
PRIMARY EXAMINER